IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Billiar et al.	Art Unit	: 1618
Serial No.	: 10/676,280	Examiner	: Blessing M. Fubara
Filed	: September 30, 2003	Conf. No.	: 7071
Title	: TREATMENT FOR HEMORRHAGIC SHOCK		

Commissioner for Patents
P.O. Box 1450
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INTERVIEW SUMMARY

Applicants' representatives (the undersigned and Janis K. Fraser) thank Examiner Blessing M. Fubara for the courtesy of the in-person interview held on July 26, 2007. The claims of the present application and the prior art of record were discussed. Applicants' representatives explained why the claims are fully enabled and are not anticipated by the prior art of record.

They addressed enablement issues raised by the Office in two separate papers, i.e., the Office Action mailed January 12, 2007 (the "Office Action"), and an Interview Summary applicants received in several related applications, including Serial No. 10/439,632 (the " '632 Interview Summary"). With regard to the issues raised in the Office Action, applicants' representatives reiterated the well-settled rule that considering whether a drug, in this case CO, can safely be administered to humans falls within the purview of the Food and Drug Administration and not the U.S. Patent and Trademark Office. They explained that Omaye (Toxicol. 180:139-150 (2002)), which describes side effects humans can experience when exposed to CO, does not truly cast any doubt on whether the claims are enabled. Applicants referred to the book Medical Toxicology, Diagnosis and Treatment of Human Poisoning, Ellenhorn and Barceloux (Eds.) Elsevier, 1988, which discusses the toxic effects of various levels of inhaled CO to support applicants' point that practitioners knew what doses of CO could be tolerated for what time periods without dangerous toxic effects. They asserted that practitioners could have used such information to avoid a dosing regimen that risked unduly dangerous effects. Applicants' representatives stressed that for any drug, what constitutes "unduly" dangerous side effects is highly dependent on the situation in which it is to be administered. As an example, they asked the Examiner to consider a patient whose life is in

immediate danger from a serious condition such as hemorrhagic shock (HS). In such a situation, potential side effects of CO exposure, such as headaches, pose a relatively minor and acceptable risk when the potential benefit is saving the patient's life. As with any other potentially toxic drug, practitioners are perfectly capable of weighing the benefits and potential risks of administering CO and administering it in accordance with the present specification. Examiner Fubara reiterated her position that publications reciting that certain levels of CO are toxic in humans demonstrate that applicants' claims are not enabled, but indicated she would consider the evidence and arguments provided in applicants' Reply to Office Action filed July 11, 2007 (hereinafter the "Reply"). The Examiner indicated that she is unlikely to find the claims enabled unless applicants narrow them to recite actual dosage amounts of CO in order to allay her concerns about the potential toxicity of CO.

With regard to enablement issues raised in the '632 Interview Summary, applicants' representatives explained that the publications recited therein do not truly cast doubt on whether the presently claimed methods are enabled. In particular, applicants pointed out that Mayr et al. (Am. J. Resp. Crit. Care Med., Vol. 171, p. 354-360, 2005 (hereinafter "Mayr")), a study that unsuccessfully attempted to detect anti-inflammatory effects of CO in humans, does not even suggest that administering CO to patients to treat HS is unpredictable. They explained that the profound differences between Mayr's studies and those of the present specification render Mayr irrelevant to the Office's determination of whether the claims are enabled. They explained that given those differences, along with applicants' positive results in the rodent models, no practitioner would accept Mayr as even suggesting that applicants' claimed methods would not work in humans or other animals. Examiner Fubara indicated that she would consider the '632 Interview Summary and applicants' arguments.

On the issue of anticipation, applicants' representatives explained why the pending claims are not anticipated by the art of record, i.e., Fujita et al. (Nat. Med. 7: 598-604 (2001); hereinafter "Fujita"), Grinstaff et al. (U.S. Patent No. 5,498,241; hereinafter "Grinstaff") and Pinsky et al. (US Publication No. 2005/0048133), for at least the reason that none teaches treatment of HS. Applicants pointed out that Bar-Or (U.S. Publication No. 2005/0215468), which was cited by the Office to support its proposition that HS and ischemia are synonymous terms, does not support such a proposition. Examiner Fubara indicated she would consider

applicants' evidence and arguments filed in applicants' Reply to Office Action filed July 11, 2007.

Applicants ask that all claims be allowed. No fees are believed to be due. Please apply any charges or credits to our Deposit Account No. 06-1050, referencing Attorney Docket Number 14022-011001.

Respectfully submitted,

Date: 8/6/07

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